8. REGULATIONS AND ADVISORIES

An acute-duration oral MRL of 0.02 mg copper/kg/day was derived for copper. This MRL is based on the occurrence of gastrointestinal disturbances in women ingesting 0.0731 mg Cu/kg/day in drinking water for 2 weeks; no adverse effects were observed at a drinking water dose of 0.0272 mg Cu/kg/day (Pizarro et al. 1999). To calculate an MRL, the copper dose provided in the drinking water was added to the average dietary intake (0.0266 mg Cu/kg/day). The total copper intake of 0.0538 mg Cu/kg/day was divided by an uncertainty factor of 3 to account for human variability.

The acute-duration oral MRL of 0.02 mg Cu/kg/day was adopted for use as the intermediate-duration oral MRL for copper.

IARC (1993) has classified copper 8-hydroxyquinoline in Group 3, unclassifiable as to carcinogenicity in humans. EPA (IRIS 2002) has classified copper in Group D, not classifiable as to human carcinogenicity.

International, national, and state regulations and guidelines regarding human exposure to copper are summarized in Table 8-1.

Table 8-1. Regulations and Guidelines Applicable to Copper

Agency	Description	Information	Reference
INTERNATIONAL Guidelines:			
IARC	Carcinogenicity classification		IARC 2002
	Copper 8-hydroxyquinoline	Group 3[a]	
NATIONAL Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA)		ACGIH 2001
	Fume (Cu)	0.2 mg/m^3	
	Dusts and mists (as Cu)	1.0 mg/m^3	
EPA	Serious health effects from ambient air exposure (Cu)		EPA 2002b 40CFR61.01(b)
NIOSH	REL (10-hour TWA)		NIOSH 2002
	Fume (as Cu)	0.1 mg/m^3	
	Dusts and mists (as Cu)	1.0 mg/m^3	
	IDLH		
	Fume, dusts, and mists (as CU)	100 mg/m^3	
OSHA	PEL (8-hour TWA) for general industry		OSHA 2002c 29CFR1910.1000
	Fume (as Cu)	0.1 mg/m^3	
	Dusts and mists (as Cu)	1.0 mg/m^3	
	PEL (8-hour TWA) for construction industry		OSHA 2002b 29CFR1926.55
	Fume (as Cu)	0.1 mg/m^3	
	Dusts and mists (as Cu)	1.0 mg/m^3	
	PEL (8-hour TWA) for shipyard industry		OSHA 2002a 29CFR1915.1000
	Fume (as Cu)	0.1 mg/m^3	
	Dusts and mists (as Cu)	1.0 mg/m^3	
b. Water			
DOT	Marine pollutant (Cu metal powder and cupric sulfate)		DOT 2002 49CFR172.101, Appendix B
EPA	Drinking water standard		EPA 2002c
	Action level (Cu)	1.3 mg/L	
	MCLG (Cu)	1.3 mg/L	EPA 2002d 40CFR141.51(b)

Table 8-1. Regulations and Guidelines Applicable to Copper *(continued)*

Agency	Description	Information	Reference
NATIONAL *(cont.)*			
EPA	Groundwater monitoring (Cu)		EPA 2002g
	Suggested method	PQL	40CFR264,
	6010	60 µg/L	Appendix IX
	7210	200 µg/L	
	Hazardous substance in accordance with Section 311 (b)(2)(A) of the Clean Water Act (cupric sulfate and cupric sulfate, ammoniated)		EPA 2002j 40CFR116.4
	Reportable quantity of hazardous substance designated pursuant to Section 311 of the Clean Water Act		EPA 2002k 40CFR117.3
	Cupric sulfate	10 pounds	
	Cupric sulfate, ammoniated	100 pounds	
	Secondary MCL for public water systems (Cu)	1.0 mg/L	EPA 2002e 40CFR143.3
	Toxic pollutant designated pursuant to Section 307(a)(1) of the Federal Water Pollution Control Act and is subject to effluent limitations (Cu and compounds)		EPA 2002a 40CFR401.15
	Water quality criteria (Cu)		EPA 1999
	Freshwater		
	CMC	13.0 µg/L	
	CCC	9.0 µg/L	
	Saltwater		
	CMC	4.8 µg/L	
	CCC	3.1 µg/L	
	Human health for consumption of water and organism	1,300 µg/L	
	Organoleptic effect criteria	1,000 µg/L	
c. Food and Drugs			
EPA	Exemption from requirement of a tolerance in meat, milk, poultry, eggs, fish, shellfish, and irrigated crops when it results from the use as an algicide, herbicide, and fungicide when used in accordance with good agricultural practices (Cu)		EPA 2002f 40CFR180.1021

Table 8-1. Regulations and Guidelines Applicable to Copper *(continued)*

Agency	Description	Information	Reference
NATIONAL *(cont.)*			
FDA	Bottled water; allowable level (Cu)	1.0 mg/L	FDA 2001a 21CFR165.110
	Clinical chemistry test system; copper test system measures copper levels in plasma, serum, and urine	Exempt from premarket notification procedures in Subpart E of Part 807	FDA 2001b 21CFR862.1190
	Color additives exempt from certification—copper powder for use in externally applied drugs	Cu not less than 95%	FDA 2001e 21CFR73.1647
	Color additives exempt from certification—copper powder for use in cosmetics		FDA 2001f 21CFR73.2647
	Direct food substance affirmed as generally recognized as safe when used as a nutrient supplement or as a processing aid (cupric sulfate)		FDA 2001c 21CFR184.1261
	Drug products containing certain active ingredients offered over-the-counter; inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses (Cu)	Weight control drug product	FDA 2001g 21CFR310.545 (a)(20)
	Trace minerals added to animal feeds as nutritional dietary supplements are generally recognized as safe when added at levels consistent with good feeding practices (Cu compounds)		FDA 2001i 21CFR582.80
IOM	Recommended dietary allowance (RDA)	0.9 mg/day	IOM 2001
d. Other			
EPA	Carcinogenicity classification (Cu) RfC RfD	Group D[b] No data No data	IRIS 2002

Table 8-1. Regulations and Guidelines Applicable to Copper *(continued)*

Agency	Description	Information	Reference
NATIONAL *(cont.)*			
EPA	Reportable quantity designated as a CERCLA hazardous substance under Section 307(a) of the Clean Water Act (Cu)	5,000 pounds	EPA 2002h 40CFR302.4
	Reportable quantity designated as a CERCLA hazardous substance under Section 311(b) (4) of the Clean Water Act (cupric sulfate)	10 pounds	EPA 2002h 40CFR302.4
	Toxic chemical release reporting; community right-to-know; effective date of reporting (Cu)	01/01/87	EPA 2002i 40CFR372.65(a)
STATE Regulations and Guidelines:			
a. Air			
Illinois	Toxic air contaminant (Cu)		BNA 2001
Louisiana	Toxic air pollutant[c] Minimum emission rate (Cu and compounds)	 25 pounds/year	BNA 2001
New Mexico	Toxic air pollutant Fume (Cu) OEL Emissions Dusts and mists (as Cu) OEL Emissions	 0.2 mg/m^3 0.0133 pounds/hour 1.0 mg/m^3 0.0667 pounds/hour	BNA 2001
Vermont	Cu compounds Hazardous ambient air standard Averaging time Action level	 100 µg/m^3 8 hours 4 pounds/hour	BNA 2001
b. Water			
Arizona	Drinking water guideline (Cu)	1,300 µg/L	HSDB 2002
North Carolina	Groundwater quality standard (Cu)	1.0 mg/L	BNA 2001
c. Food	No data		

Table 8-1. Regulations and Guidelines Applicable to Copper *(continued)*

Agency	Description	Information	Reference
STATE *(cont.)*			
d. Other			
Arizona	Soil remediation levels (Cu and compounds) Residential Non-residential	 2,800 mg/kg 63,000 mg/kg	BNA 2001
Florida	Toxic substance in the workplace (Cu fume, dust, and mist)		BNA 2001

[a]Group 3: unclassifiable as to carcinogenicity to humans
[b]Group D: not classifiable as to human carcinogenicity
[c]Class II: suspected human carcinogen and known or suspected human reproductive toxin

ACGIH = American Conference of Governmental Industrial Hygienists; BNA = Bureau of National Affairs; CERCLA = Comprehensive Environmental Response Compensation and Liability Act; CFR = Code of Federal Regulations; CCC = criterion continuous concentration; CMC = criteria maximum concentration; Cu = copper; DOT = Department of Transportation; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; HSDB = Hazardous Substances Data Bank; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life and health; IOM = Institute of Occupational Medicine; IRIS = Integrated Risk Information System; MCL = maximum contaminant level; MCLG = maximum contaminant level goal; NIOSH = National Institute for Occupational Safety and Health; OEL = occupational exposure limit; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limits; PQL = practical quantitation limits; RDA = recommended dietary allowance; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; TLV = threshold limit value; TWA = time-weighted average